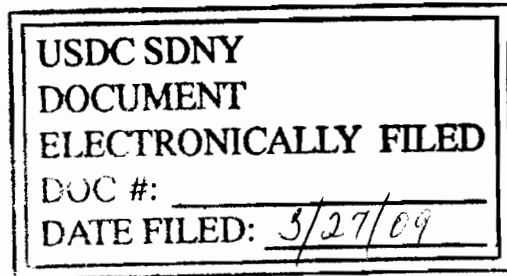


UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK



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AXONYX SECURITIES LITIGATION  
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05 Civ. 2307 (TPG)

**OPINION**

Plaintiffs in this class action assert that Axonyx and two of its executives violated the federal securities laws by making misleading statements regarding a drug being developed by Axonyx. Defendants have moved to dismiss the complaint under Rule 12(b)(6). The motion is granted.

Facts

The following facts are taken from the complaint and, for the purpose of this motion, are assumed to be true, although the court finds that they are not sufficient to make out certain essential elements of plaintiffs' case.

Axonyx was a pharmaceutical company focused on developing a drug to treat Alzheimer's disease. Most of its research was directed to a drug known as Phenserine. On June 26, 2003, Axonyx announced that it was beginning its first Phase III clinical trial of Phenserine. A Phase III trial is the final phase of drug testing before seeking approval of a new drug by the Food and Drug Administration. Phase III trials involve a

relatively large number of patients and are intended to confirm both the efficacy and safety of a drug. A successful Phase III trial would make FDA approval of Phenserine more likely, though not guaranteed.

The first Phase III trial of Phenserine was conducted at eleven sites in Europe with 375 patients. The patients were randomly assigned to receive either a placebo, 10mg of Phenserine, or 15mg of Phenserine. The study was “double-blind,” so neither the patients nor their physicians knew which group a patient was assigned to. The effectiveness of the drug was assessed by tracking the patients’ performance on various tests of memory and cognition. If the patients receiving Phenserine performed meaningfully better on these tests than the patients receiving the placebo, that would indicate that the drug was effective. In June and November 2004, Axonyx announced that it had initiated two more Phase III trials, and that it planned to enroll 450 patients in each.

During this period, Axonyx raised at least \$95 million through private placements of its securities that occurred on September 12, 2003 (three months after the announcement of the first Phase III trial), January 8, 2004, and May 4, 2004.

In December 2004, defendant Bruinsma sold 215,000 shares of Axonyx stock, or about 30% of his holdings, at a profit of \$1.5 million. From September 2004 to January 2005, defendant Hausman sold

122,500 shares of stock, or about 5% of his holdings, at a profit of \$766,000. Neither had sold any other Axonyx stock since June 2001.

On February 7, 2005, Axonyx announced that the first Phase III trial had failed to demonstrate that Phenserine was effective at treating Alzheimer's. Specifically, patients treated with the drug had not shown "a statistically significant improvement" in their cognition and memory tests when compared to patients treated with a placebo. That day, the price of Axonyx stock dropped from \$4.85 per share to \$1.81 per share.

On March 11, Axonyx announced that it had suspended recruitment of new patients for its second and third Phase III trials, and that the company was reevaluating the study designs. On September 20, Axonyx announced that these two trials had also failed to show Phenserine's effectiveness. That day, the stock's price dropped from \$1.24 per share to \$1.09 per share. By December 22, NASDAQ informed Axonyx that it no longer met NASDAQ's listing standards, since its stock price had been below \$1.00 per share for over 30 consecutive business days.

#### Plaintiffs' Contentions

The complaint alleges that Axonyx and the individual defendants violated section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5 by making misleading statements about the Phase III trials. The complaint also alleges that the individual defendants are liable under section 20 of the Exchange Act, 15 U.S.C. § 78t, as control

persons for misstatements by Axonyx. Finally, the complaint alleges that the individual defendants are liable under section 20A of the Exchange Act, 15 U.S.C. § 78t-1, for insider trading.

In support of their claim under section 10(b) and Rule 10b-5, plaintiffs allege that the first Phase III trial suffered from numerous flaws that prevented it from showing Phenserine's effectiveness. First, Axonyx only enrolled 375 patients in the trial, but, according to plaintiffs, should have enrolled 600. Because the trial was too small, it did not have the statistical "power" necessary to show a difference between Phenserine and the placebo. Second, the cognitive tests were improperly administered to certain patients because they were not administered in the patients' native languages. Third, certain patients who were assigned to the placebo group, and should therefore not have received Phenserine, showed traces of Phenserine in their blood during subsequent tests. Plaintiffs allege that Axonyx and its executives knew, or recklessly disregarded, that these deficiencies existed and would undercut the ability of the study to demonstrate Phenserine's effectiveness.

According to plaintiffs, statements made by defendants between June 2003 and December 2004, in press releases and SEC filings, were misleading because they failed to disclose these flaws in the trial's design. These statements can be grouped into six general categories. First, defendants stated that the trial was intended to demonstrate the safety and efficacy of Phenserine. Second, they stated that the trial

would employ “standard memory and cognition tests recommended by” the FDA. Third, based on results from prior studies of Phenserine and chemically similar drugs, defendants indicated that Phenserine was likely to be found safe and effective, and was therefore a good candidate for FDA approval. Fourth, they indicated that Axonyx was “pleased with the progress” of the Phase III trial and, based on additional funding received in May 2004, was “well positioned to complete the clinical development of Phenserine.” Fifth, they referred to the clinical trial as “pivotal.” Sixth, they indicated that they had “completed enrollment” in the first clinical trial.

#### The Section 10(b) Claim

Section 10(b) of the Exchange Act makes it unlawful to use “any manipulative or deceptive device” in connection with the purchase or sale of a security. 15 U.S.C. § 78j(b). Pursuant to SEC Rule 10b-5, it is unlawful to “make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.”

To maintain a private action under section 10(b) and Rule 10b-5, a plaintiff must allege, among other things, facts “giving rise to a strong inference” that the defendant acted knowingly or recklessly in making misleading misrepresentations or omissions. Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005); ECA v. J.P. Morgan Chase Co.,

553 F.3d 187, 198 (2d Cir. 2009); 15 U.S.C. § 78u-4. To show recklessness, a plaintiff must show that defendants made statements under circumstances where it should have been obvious to them “that they were misrepresenting material facts related to the corporation” because they knew or had access to information contradicting their public statements. Novak v. Kasaks, 216 F.3d 300, 308 (2d Cir. 2000). However, “as long as the public statements are consistent with reasonably available data, corporate officials need not present an overly gloomy or cautious picture of current performance and future prospects.” Id. at 309.

To determine whether the complaint raises a “strong inference” of scienter, courts must “take into account plausible opposing inferences” to determine whether the inference of scienter is “cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2509-10 (2007). A strong inference can be generated by facts showing either “the motive and opportunity to commit fraud” or strong circumstantial evidence. ECA, 553 F.3d at 198-99. As with any motion to dismiss for failure to state a claim, a court must accept the facts stated in the complaint as true. Id.

The allegation of securities fraud here is premised on plaintiffs’ belief that defendants did not design the first Phase III trial properly. Unlike more conventional securities fraud cases, plaintiffs do not claim

that defendants engaged in accounting manipulations, or that they concealed the negative results of the first Phase III trial. Instead, they claim that defendants knew or recklessly ignored the fact that the clinical trial was defective, and that any statements about the trial's progress were therefore necessarily misleading. But it must be said that the chances of this kind of thing actually occurring are surely remote. The idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly carry on a defective trial—so that any defects were not remedied—virtually defies reason, unless the company was bent on defrauding the FDA and the suffering people who might use the drug. Nothing of that sort is even suggested in the complaint.

Turning to the complaint, it does not allege that any statements issued by defendants were actually untrue. To the contrary, the statements challenged by plaintiffs were accurate on their face, as plaintiffs themselves admit. Plaintiffs agree that the Phase III trials were intended to demonstrate the safety and efficacy of Phenserine, were “pivotal” to the success of Axonyx, and used standard memory and cognition tests. Plaintiffs do not allege that Axonyx was untruthful about having completed enrollment in the first Phase III trial or about expecting to complete it within a short timeframe. Finally, defendants' statements that Phenserine was likely to be an effective, marketable drug were based on evidence that at the time suggested this very thing.

However, as already indicated, plaintiffs allege that statements by defendants were misleading in that defendants knowingly or recklessly failed to disclose that the Phase III trials were defective. For the sake of this motion to dismiss, the court will accept as true the allegations about defects in the Phase III trials. But it must be recognized that the allegations relate to matters of opinion and are not strongly supported.

It is clear that there is no sufficient pleading of scienter regarding the so-called defects. To support their argument that defendants knowingly made misleading statements, plaintiffs point to four pieces of circumstantial evidence. First, they note that Axonyx, in preparing for the first Phase III trial, sought to minimize its cost by, for instance, choosing the lowest bidder to run the trial. However, nothing in the complaint supports an inference that such cost-cutting meant that defendants knew that there would be some flaw in the trial or that the trial would fail. Indeed, minimizing the costs of the trial was surely rational for Axonyx, which plaintiffs themselves allege was a relatively small company and depended on the success of Phenserine, a product that, while of great importance to the company, was still far from coming to market.

Second, plaintiffs note that Axonyx used the announcement of the clinical trial to entice investors to participate in the company's private placements. Plaintiffs contend that the company's goal was to secure operating capital that would allow it to be acquired later. It is

conceivable that there might be a case involving a “hidden agenda” about seeking to be acquired that could render the announcement of a clinical trial misleading. However, the allegations in the complaint here indicate that Axonyx was, as it said, embarking on the Phase III trial, and seeking financing for its continuing efforts to develop Phenserine as a marketable product. No real basis is pleaded for a “hidden agenda” claim.

Third, plaintiffs note that the individual defendants sold some Axonyx stock just weeks before the announcement of the disappointing results of the first Phase III trial. However, these sales still left the individuals with substantial holdings in Axonyx stock, and therefore a considerable stake in ensuring the company’s success.

Fourth, plaintiffs allege that the CEO of the consulting firm hired to design the first Phase III trial informed Axonyx that the trial should include a larger number of participants. However, the Axonyx scientific advisory board nonetheless approved the design of the trial. The possible difference of opinion between the CEO and the advisory board offers no basis for a finding of scienter on the part of defendants.

Any inference of scienter suggested by the complaint is, to say the least, significantly less compelling than the opposing inference—that Axonyx did its best to design and carry out a successful clinical trial, but that despite these best efforts, Phenserine was not an effective drug to treat Alzheimer’s disease. The complaint does not contain anything approaching a plausible claim of knowing or reckless defects in the

clinical trial concealed from the investing public—something that would be a bizarre departure from any normal method of doing business.

The claims under section 10(b) are therefore dismissed.

#### The Section 20 and 20A Claims

The dismissal of plaintiffs' claims under section 10(b) requires that their claims under sections 20 and 20A be dismissed as well.

Section 20 of the Exchange Act provides that control persons are liable for Exchange Act violations by a primary violator. 15 U.S.C. § 78t(a). In order to establish control-person liability, a plaintiff must show a primary violation by the controlled person. SEC v. First Jersey Secs., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996). Plaintiffs allege that the individual defendants are liable under section 20 for the violations of section 10(b) by Axonyx itself, since they controlled the statements made by Axonyx. However, since the section 10(b) claims against Axonyx fail, the section 20 claims against the individual defendants must fail as well.

Section 20A of the Exchange Act provides that “[a]ny person who violates any provision of [the Exchange Act by] . . . selling a security while in possession of material, nonpublic information shall be liable” to contemporaneous purchasers of the same securities. 15 U.S.C. § 78t-1(a). To state a claim under this section, a plaintiff must plead a viable predicate violation of the Exchange Act. Jackson Nat’l Life Ins. Co. v. Merrill Lynch & Co., 32 F.3d 697, 703 (2d Cir. 1994). Plaintiffs assert that the individual defendants’ liability under section 10(b) gives rise to

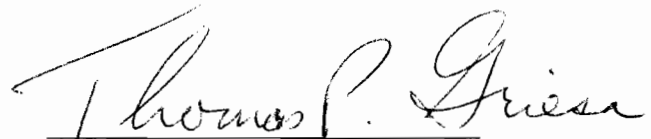
liability under section 20A as well, since these defendants sold Axonyx stock at the same time that class members purchased stock. However, since the section 10(b) claims against the individual defendants fail, the section 20A claims against them must also be dismissed.

Conclusion

Defendants' motion to dismiss is granted in its entirety.

SO ORDERED.

Dated: New York, New York  
March 27, 2009

A handwritten signature in black ink, reading "Thomas P. Griesa". The signature is written in a cursive style with a horizontal line underneath the name.

Thomas P. Griesa  
U.S.D.J.